EXHIBIT BB

The Drug Development Process

Step 1
Discovery and
Development

Discovery and Development (/patients/drug-development-process/step-1-discovery-and-development)
Research for a new drug begins in the laboratory.

More Information (/patients/drug-development-process/step-1-discovery-and-development)

Step 2
Preclinical Research

Preclinical Research (/patients/drug-development-process/step-2-preclinical-research)
Drugs undergo laboratory and animal testing to answer basic questions about safety.

More Information (/patients/drug-development-process/step-2-preclinical-research)

Step 3
Clinical Research

Clinical Research (/patients/drug-development-process/step-3-clinical-research)
Drugs are tested on people to make sure they are safe and effective.

More Information (/patients/drug-development-process/step-3-clinical-research)

Step 4
FDA Review

FDA Review (/patients/drug-development-process/step-4-fda-drug-review)
FDA review teams thoroughly examine all of the submitted data related to the drug or device and make a decision to approve or not to approve it.

More Information (/patients/drug-development-process/step-4-fda-drug-review)

Step 5
FDA Post-Market
Safety Monitoring

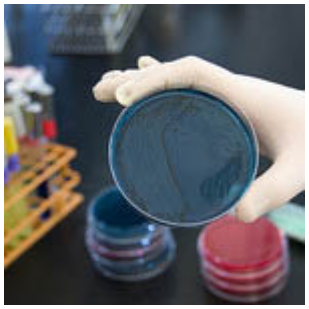
FDA Post-Market Safety Monitoring (/patients/drug-development-process/step-5-fda-post-market-drug-safety-monitoring)
FDA monitors all drug and device safety once products are available for use by the public.

More Information (/patients/drug-development-process/step-5-fda-post-market-drug-safety-monitoring)

Step 2: Preclinical Research

Before testing a drug in people, researchers must find out whether it has the potential to cause serious harm, also called toxicity. The two types of preclinical research are:

- In Vitro



- In Vivo

FDA requires researchers to use good laboratory practices (GLP), defined in medical product development regulations, for preclinical laboratory studies. The GLP regulations are found in 21 CFR Part 58.1: Good Laboratory Practice for Nonclinical Laboratory Studies (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58). These regulations set the minimum basic requirements for:

- study conduct
- personnel
- facilities
- equipment
- written protocols
- operating procedures
- study reports
- and a system of quality assurance oversight for each study to help assure the safety of FDA-regulated product

Usually, preclinical studies are not very large. However, these studies must provide detailed information on dosing and toxicity levels. After preclinical testing, researchers review their findings and decide whether the drug should be tested in people.